REMARKS/ARGUMENTS

1. Status of the claims

With entry of this amendment, claim 1, 15, 29, 32, 33, 49 and 63 are amended. Claims 2, 5, ,6, 7, 8, 10, 12, 14, 28, 35, 37, 40, 42, 46, 47, 48 and 62 are canceled. Claims 11, 13, 17-27, 30-31, 36, 51-61 and 64-65 were previously withdrawn from consideration by the Examiner. Claims 1, 3, 4, 9, 15, 16, 29, 32, 33, 34, 39, 41, 43, 44, 45, 49, 50, and 63 are pending and under consideration with entry of the Amendment.

2. Support for amendments to the claims

Support for the amendments to the claims can be found throughout the specification, the drawings, and the claims as originally drafted. For example, support for "90% identity" can be found on, e.g., page 8, line 14 of the specification. No new matter is introduced.

3. Rejection under 35 U.S.C. § 112, second paragraph

Claim 1 was rejected as allegedly indefinite for reciting "ectopically." The Examiner suggested that the Applicants replace the term with "over-expressed."

Applicants submit that the term "ectopic expression" is used regularly in the art and that there is no ambiguity in the term. "Ecoptic expression" refers to enhanced expression in a tissue where the gene product is expressed in a wild type plant, or any expression in a tissue where there is no expression in a wild-type plant. In addition, "ectopic expression" also refers to expression at a time or stage of growth other than what occurs in wild-type. Accordingly, Applicants respectfully request withdrawal of the rejection.

The Examiner objected to the term "gene product," as allegedly indefinite. Applicants note that the term is defined as interchangeable with the terms "protein" and "polypeptide." *See*, page 63, lines 1-8 of the specification. Therefore, Applicants submit that the term is not indefinite.

The Examiner objected to the phrase "at least 50%" and requested that Applicants replace the phrase with "exhibiting at least 50% sequence identity." Applicants have amended

the claims as the Examiner has suggested. Therefore, Applicants request withdrawal of the rejection.

The Examiner rejected claim 2 for reciting "early" without indicating the comparative basis. As amended, the claims address this issue.

Claims 7-8 were rejected for reciting the term "modified." To expedite prosecution, claims 7-8 are canceled, thereby rendering the rejection moot.

Claims 28 and 29 are amended as the Examiner suggested.

The Examiner alleged that the term "modulating," as used in claim 32, is unclear. As amended, the word "modulating" does not occur in the claims, thereby rendering the rejection moot.

The Examiner also rejected claim 32 because the claim allegedly did not result in modulations of timing. As amended, the claim recites that the plant produced has early reproductive development.

The Examiner also requested minor wording changes to a number of claims. To the extent appropriate, the amended claims reflect the suggested changes.

Accordingly, Applicants respectfully request withdrawal of the rejections.

4. Rejection under 35 U.S.C. § 112, first paragraph:written description

Claims 11-10, 12, 14-16, 28-29, 32, 33-50 and 62-63 were rejected under 35 U.S.C. § 112, first paragraph. According to the Examiner, the specification does not provide a description of the full scope of the claims. Applicants respectfully traverse the rejection.

The Federal Circuit has held that the written description requirement can be fulfilled in any number of ways, so long as the specification describes the invention "in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention." *See University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997). For a chemical invention, an adequate description "requires a precise definition, such as by ***structure***, formula, chemical name, or ***physical properties***...." (emphasis added). Accordingly, as described below, the present specification provides ample written description for the pending claims, precisely as required by the Court in *University of California*.

In the present case, the amended independent claims encompass methods or compositions involving polynucleotides encoding a gene product at least 90% identical to SEQ ID NO:2 or 32, wherein the gene products result in decreased timing of reproductive development when expressed in a plant. The gene products recited in the amended claims are defined by identity (90%) to recited sequences. Percent identity to a particular sequence reflects the relation of the nucleotide sequence to the recited sequence. Thus, the specification defines a *physical* and *structural property* of the invention, as explicitly required by the court in *University of California.*

Moreover, each claim only encompasses polynucleotides encoding polypeptides with a particular function, i.e., the ability to decrease timing of reproductive development. Thus the amended claims are defined by *structure* and *function.*

Accordingly, Applicants therefore respectfully request withdrawal of the rejection.

5. Rejection under 35 U.S.C. § 112, first paragraph:enablement

Claims 1-10, 12, 14-16, 28-29, 32-50 and 62-63 were rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled. Specifically, the Examiner argued that undue experimentation was required to identify sequences encoding gene products at least 50% identical to recited sequences. *See*, Office Action, page 7. In addition, the Examiner argued that undue experimentation was required to modify a gene regulatory element. *See*, Office Action, page 9. Finally, the Examiner argued that decreasing reproductive timing was enabled but increasing reproductive timing was not. *See*, Office Action, page 10.

Applicants respectfully traverse the rejection. The amended claims, directed to methods or compositions involving polynucleotides encoding a gene product at least 90% identical to SEQ ID NO:2 or 32, do not require undue experimentation. Moreover, as amended, the claims do not recite "modified" regulatory elements or increasing timing of reproductive development, thereby rendering that part of the rejection moot.

The proper test of enablement is "whether one skilled in the art could make or use the claimed invention from the disclosure in the patent coupled with information known in the

art without undue experimentation." *See, e.g.*, MPEP § 2164.01. As identified by the Patent Office and the Federal Circuit, whether undue experimentation is required by one skilled in the art to practice the invention is determined by considering factors such as the amount of guidance presented in the application and the presence of working examples. *See Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1985); *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). As described in *Wands*, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should precede." *Wands*, 8 USPQ2d at 1404 (quoting *In re Jackson*, 217 USPQ 804 (Bd. Pat. App. & Int. 1982).

The claims were rejected because identification of polynucleotides with the recited function allegedly requires undue experimentation. In support of this assertion, the Examiner cited Krizek *et al.* The assertion that undue experimentation is necessary is not correct for two reasons.

First, Krizek *et al.*, if anything, provides some direction about how much can be changed in protein sequences while retaining function. Krizek *et al.* demonstrates that large domains can be swapped between MADS box proteins while retaining at least some activity. This suggests that point mutations, especially those informed by knowledge of other MADS box sequences as discussed below, would not greatly affect activity. Moreover, the sequence changes that did alter function could be easily identified and discarded. Thus, undue experimentation is not required to make and use the recited sequences.

Second, Krizek *et al.* was written five years before the filing date of the present application. Therefore Krizek *et al.* does not reflect the state of the art at the time the application was filed.

As discussed above, the test for enablement is based on the disclosure of the patent application combined with information known in the art. Applicants submit that the present application provides ample detail to identify and isolate polynucleotides of the invention. For example, on pages 20-25, the specification describes the structure and function of various MADS box gene products. As of 2001, the year the application was filed, a large number of MADS box-containing gene products were known. Moreover, in 2001 it was routine to

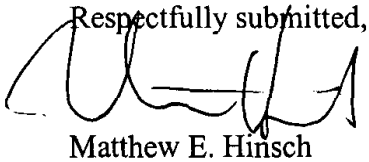
compared amino acid sequences to identify conserved and divergent sequences and thereby introduce changes into proteins while retaining activity. While not all sequences tested would be active, there is no reason to believe that screening of a relatively small number of sequences would not lead to identification of variants with activity. Therefore, it would only take routine experimentation to identify and isolate the recited polynucleotide sequences.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Matthew E. Hinsch
Reg. No. 47,651

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
MEH:meh
11468550 v1